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Level of Amputation Following Failed Arterial Reconstruction Compared to Primary Amputation – a Meta-analysis

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Objectives: *to determine if the level of amputation after failed vascular reconstruction was comparable to the level of amputation after primary amputation.*
Design and methods: *medline literature search (1975–1996), meta-analysis.*
Results: *the odds ratio of transtibial to transfemoral (TT/TF) amputations was 927/657 = 1.41 (95% confidence limits: 1.278–1.561) in postrevascularisation amputation (PRVA) and 1590/1162 = 1.37 (95% confidence limits: 1.269–1.477) in primary amputation (PA) (p = 0.65). The pooled data show that the number of conversions from transtibial (TT) to transfemoral (TF) amputations due to amputation stump complications were 85/369 (23%) in PRVA against 93/752 (12.4%) in PA (p<0.01).*
Conclusions: *we could not detect any difference in TT/TF ratio between PRVA and PA. However, the risk of conversion i.e. reamputation to a higher level is higher after PRVA compared to PA. The chance of having a successful transtibial amputation is approximately 58% for postrevacularisation amputation as well as for primary amputations. An aggressive approach towards vascular reconstruction seems justified.*

Key Words: Failed arterial reconstruction; Amputation; Level of amputation.

Introduction

In recent years a number of reports have documented a falling incidence of major amputation for vascular disease, including diabetes, coinciding with an increase in vascular surgical activity.[1–7] Reductions of 50–65% has been documented in local areas and 18 to 28% in nationwide statistics.[1,2,8] Decreases of 40–85% in diabetic amputations have recently been reported[9] and a reduction of 40% according to Danish national statistics.[10] These results are significant, since epidemiological studies previously reported an increasing incidence or, at best, a levelling of amputation rates.[11–16]

The increasing number of vascular reconstructions in critical ischaemia has also been followed by an increasing number of amputations following unsuccessful or temporarily successful revascularisation.[2,17] Failed revascularisation may cause a deterioration in the condition of the skin and arterial supply. The possibility of performing a below-knee, i.e. transtibial (TT) amputation, may then be lost resulting in an above-knee, i.e. transfemoral (TF) amputation. This reduces the potential for rehabilitation with a prosthesis.

The lack of any randomised controlled studies led us to perform a structured and systematic review of the literature. Our goal was to determine if the outcome regarding the level of amputation after PRVA and PA were comparable. Meta-analysis is a method for pooling data to increase statistical power for defined end points and subgroups. Furthermore, it is a way of systematically analysing conflicting reports and may also answer new questions that were not considered in the original reports.

Material and Methods

We used the normal procedure for conducting a meta-analysis, i.e. ask a specific question, define inclusion and exclusion criteria for eligible reports, perform an exhaustive search and summarise the eligible published literature. Most meta-analyses are limited to

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Table 1. Primary amputations (PA).

Authors	*n* =	TT		TF	TT/TF
		Heeled	Conv		
Burgess (1975)[14]	135	113		22	5.1
Samson (1985)[24]	161	81		80	1.0
Gregg (1985)[21]	178	77	15	101	0.8
Larsson (1988)[20]	161	129		71	1.8
Ebstein (1989)[41]	43	27	1	16	1.7
Evans (1990)[30]	551	283	36	268	1.1
Ellitsgaard (1990)[21]	256	114	15	135	0.8
Tsang (1991)[13]	50	28		24	2
Cook (1992)[35]	316	158	26	148	1.1
Crouch (1992)[45]	271	160		111	1.4
Stirnemann (1992)[27]	83	72		11	6.6
Stewart (1993)[40]	305	220		85	2.6
Campbell (1994)[42]	228	128		100	1.3

Table 2. Postrevascularisation amputations (PRVA).

Authors	*n* =	TT		TF	TT/TF
		Heeled	Conv		
Schlenker (1975)[24]	46	27	9	19	1.4
Burgess (1975)[13]	137	105		32	3.3
Katzmer (1980)[29]	40	21	10	19	1.1
Dardik (1982)[22]	79	39	11	40	1
Wooster (1982)[23]	35	17	2	18	0.9
Brewster (1983)[43]	67	41		26	1.6
Gregg (1985)[33]	46	22		24	0.9
Bloom (1988)[42]	12	9		3	3.0
Larsson (1988)[20]	100	52		48	1.1
Ebstein (1989)[41]	32	9	3	23	0.4
Evans (1990)[30]	210	110	37	100	1.1
Tsang (1991)[18]	60	31	6	27	1.2
Taylor (1991)[44]	41	31		10	3.1
Cook (1992)[35]	63	30	7	33	0.9
Crounch (1992)[45]	193	33		41	0.8
Stirnemann (1992)[27]	103	72		31	2.3
Stewart (1993)[40]	372	239	133	1.8	
Campbell (1994)[42]	69	39		30	1.3

randomised, controlled trials. However, such studies do not exist, therefore we broadened our inclusion criteria and analysed non-randomised comparative studies and uncontrolled case series.

Search

The minimum eligibility criteria were defined before we conducted a medline search of the literature on level of amputation after primary amputation and level of amputation after failed vascular reconstruction published between 1975 and 1996. A report was considered eligible when there was a clear description of the level of amputation. Several reports were rejected from the PA group because it was not clearly defined if the material included amputations after failed vascular surgery. We had to include a broad spectrum of vascular procedures including non-reconstructive procedures such as embolectomies because many studies included such procedures without leaving any possibility to separate the data. Both diabetic and non-diabetic amputations were included. We analysed only reports written in English. The citations found by the medline search were reviewed by the authors and numerous papers were excluded immediately on the basis of information in the abstract. In case of doubt the complete report was obtained and reviewed by the authors. The methological problems are described in the discussion.

Results

Search of the literature

The medline search of the literature revealed 234 citations. Twenty references included information specifically on (final) level of amputation for true primary (i.e. amputations in patients without any vascular surgery procedures) and PRVA. These 20 papers could be used for pooling of data. The remaining references included other valuable information.

Ratio TT/TF (odds)

Most papers concerning risk of lost amputation levels compared the TT/TF ratio (i.e. odds). Only a few studies included through-knee (TK) amputations.[2,18,21,27,28] We included the TK amputation numbers in the TT group. The higher the ratio for the final levels, i.e. after conversions, the better. Tables 1 and 2 listing available results demonstrate a great variation in the ratio for both groups, in particular in the PA group. When recalculating the pooled data the odds in the PA group were 1590/1162 = 1.37 (95% confidence limits 1.269–1.477) and in the PRVA group the odds were 927/657 = 1.41 (confidence limits 1.278–1.561), ($p = 0.65$).

Tables 1 and 2 also list the number of failed TT amputations converted to TF level. The conversion rate for the pooled data was higher after PRVA; i.e. 85/369 (23%) as compared with 93/752 (12.4%) after PA ($p<0.01$).

Discussion

Several related issues including methological problems must be discussed and analysed before discussing the most important finding from the meta-analysis. Practically all available reports comparing the level of PRVA with the level of PA are retrospective; a few are prospective but not randomised. In principle, PRVA is performed in a selected subgroup of all patients undergoing amputation for vascular disease including diabetics. We have focused on one parameter, i.e. level of amputation, a dichotomous data, thus reducing the risk of bias.

The time interval between arterial reconstruction and amputation is an important factor to notice when evaluating the papers. Tsang *et al.*[18] documented that the longer the time interval between the arterial reconstruction and the amputation, the better the chance for TT rather than TF amputation. With PRVA later than 250 days after the original revascularisation the fraction of TT increased to more than 80%. Similar figures were found by Samson *et al.*[19] dividing the PRVAs in groups amputated within or later than 3 months after the revascularisation. Another very important factor is related to the vascular procedure, i.e. if the surgery is acute or an elective procedure. In chronic critical ischaemia the damage to the tissues is often localised to the distal parts of the limb. In acute ischaemia major parts of the limb present with critical hypoperfusion and the level of amputation tend to be more proximal. Two papers[20,21] demonstrate about 80% TF amputations in PA as well as in PRVA. Moreover, mortality is increased as often due to the coexisting cardiac morbidity.

Both the localisation of the distal anastomosis and the prosthetic material are factors of importance, but are not always specified. The work of Dardik *et al.*[22] demonstrate this. They analysed 520 arterial reconstructions with umbilical veins for critical ischaemia with 79 (15.2%) PRVA. Of the 79 PRVA, 51 were TT amputations; however, 12 were converted to TF amputations due to stump complications (5/15 (33%) in the femoropopliteal group, 4/18 (22.2%) in the femoroperoneal and 3/18 (17%) in the femorotibial group). The final level was TT in only 44% after femoropoplital reconstructions and 54% and 71% after femoroperoneal and femorotibial procedures, respectively. Wooster[23] retrospectively analysed 181 femoropopliteal or more distal bypass reconstructions. Sixty-eight grafts occluded and 35 PRVA were recorded. The overall TT/TF ratio was 17/18 = 0.9. In the femoropopliteal PRVA group the odds were 11/14 = 0.8, and in the PRVA group with more distal grafts the odds were six out of four = 1.5. Thus, failed femoropopliteal reconstructions are more detrimental to amputation level than infrapopliteal reconstructions. Concerning prosthetic material, it is well-known that synthetic grafts are more likely to fail than autologous vein grafts. Schlenker and Wolkoff[24] reported that synthetic grafts (Dacron or PTFE) material as used in 29% in their series were found in almost half of the cases with PRVA. The TT/TF ratio was 3.2 in autologous vein cases and four after the use of synthetics. Wooster[23] also found a greater TT/TF ratio after reconstructions with artificial grafts than with vein grafts, i.e. four compared to 3.8. This is probably because synthetic grafts require little dissection for implantation compared to vein grafts which require harvesting.

The question about how the type of department/level of speciality influences the level of amputation was analysed by Ebskov.[25] Three different types of departments in Denmark were analysed. It was found that the knee was retained more often in specialised departments. The importance of specialisation and the attitude of the surgeons was demonstrated. It is inevitable that both amputation surgery and vascular surgery has improved during the last decades. In 1939 Homans stated that "amputation below the knee can almost never be expected to offer a healthy stump".[26] But in the 1950–1970s a series of European and American publications documented the excellent performance of TT amputations as well as through knee (TK) amputations. From the 1970s a number of

methods for objective determination of amputation level have appeared, and today there is a general awareness of the importance of saving the knee.

Several other factors seem to influence outcome: Schlenker and Wolkoff[24] analysed a number of factors such as indication (i.e. intermittent claudication, ulceration, gangrene and rest pain), the presence of diabetes and angiographic findings. In this investigation none of the factors, however, influenced the level in PRVA. Information on the significance of the amputation regime including preoperative treatment, creation of flaps, choice of wound dressings and stump treatment comparing PRVA and PA has not been found. In a recent prospective series of 117 major amputations[31] multivariate regression analysis was employed to elucidate significant factors affecting healing and level of amputation. Healing in PRVA was not different from healing in PA, but the level selection in the two groups were not indicated.

In a few papers the peripheral blood pressure as measured by Doppler ultrasound or a blood pressure cuff was recorded before arterial reconstruction and/or before PA. Katzmer[29] compared 40 PRVA with 51 PA. At pressures above 60 mmHg the healing at TT level was 17/33 (52%) in PRVA and 39/45 (87%) in PA. Below 60 mmHg the healing was four out of seven (57%) and 0.6 (0%), respectively. Evans *et al.*[30] published 56 PRVA divided into early PRVA and late PRVA according to a time interval between reconstruction and amputation of 3 months. These were compared with 132 PA. At a popliteal blood pressure above 60 mmHg the healing rate at TT before 3 months, after 3 months and for PA was 31/51 (61%), 39/61 (64%) and 108/118 (92%), respectively. Below 60 mmHg the healing was 0.5 (0%), 5/17 (29%) and 6/14 (43%). The knee salvage rate in both of these groups was thus higher after PA than after PRVA. Whether collateral circulation had deteriorated after failed arterial reconstruction could not be evaluated, since the popliteal pressure had not been measured after failed arterial reconstruction. Stirneman *et al.*[27] measured the ankle systolic blood pressure index before and after arterial reconstruction in PRVA cases and before PA. The index decreased from 0.27 to 0.13 along the line of reconstruction, i.e. indicating surgical damage to collaterals or more widespread thrombotic occlusion. Ravioli *et al.*[32] evaluated 143 cases of critical ischaemia treated with arterial reconstruction. With the aid of preoperative ankle blood pressure index the outcome of theoretical PA was estimated: 104 cases for TT and 39 for TF amputation. In the "TT group" the leg was saved in 76 (73%) and in the "TF group" in 21 (54%). In the "TT group" 28 came to PRVA and 11 of these were TF amputations. In the "TF group" 18 cases came to PRVA. Of these, only 10 were at the TF level. Thus there were 11 unexpected TF but out of the theoretical 39 TF only 10 cases actually occurred and eight (24.5%) cases were TT amputations, i.e. a more distal level. The authors concluded that the unexpected 11 TF levels were outweighed by the 97 (68%) saved legs and the fact that total TF number was only 21 instead of 39.

Gregg[33] investigated the possible influence of failed arterial reconstruction on rehabilitation. In the PRVA group walking with a prosthesis was obtained in 78% and in the PA group in 41%. The rehabilitation rates in TT amputees were in PRVA: 16/18 (89%) and in PA: 29/44 (66%). In the TF group they were PRVA: 8/13 (62%) and PA: 1/30 (3%). The favourable results in PRVA reflect probably overall better health of patients selected for arterial reconstruction.

There seems to be an inverse relation between increase in the activity of vascular surgery and the TT/TF ratio. In a 10-year series on 1167 amputations Pedersen *et al.*[2] documented a 50% reduction in the incidence of major amputation after introduction of infrapopliteal bypass. The TT/TF ratio, however, decreased simultaneously and significantly from 1.12 to 0.67. It was calculated that amputation had been avoided in 140 legs at the expense of 11 TT amputations converted to TF level.

The concern that failed vascular surgery adversely affects the level of amputation has been used as an argument against aggressive limb salvage. The lack of true randomised studies and the existence of mostly retrospective and only a few prospective studies indicate that meta-analysis was the best way to unveil the probable answer to the central question. Our meta-analysis could not support the claim that patients with PRVA end up with a higher amputation level than patients undergoing amputation without any attempt to save the limb, in as much as the odds ratio in the PA group 1.37 (95% confidence limits 1.269–1.477) did not differ significantly ($p = 0.65$) from the odds ratio 1.41 in the PRVA group (confidence limits 1.278–1.561). The chance of a healed TT amputation was approximately 58% in both groups.

PA are mostly performed in patients unsuitable for arterial reconstruction, i.e. with no capacity for walking or standing, with severe chronic mental organic deficiency or with poor health from a number of chronic diseases. These conditions are more frequent in elderly people and are often criteria used for selection of primary transfemoral amputation. Patients are also selected for PA because arterial reconstruction is technically unfeasible, which is probably again more frequent in the elderly patients. Thus the health condition

tends to be poorer in the PA compared with the PRVA group. These considerations are substantiated by the lower postoperative mortality[18,34,35] and the better chance of rehabilitation with a prosthesis in PRVA.[33] Diabetics are younger when they come to amputation[2] and they can more frequently heal a TT amputation.[8] On the other hand, the mortality in diabetics is high.[10] Diabetics are more often technically unfeasible for arterial reconstruction and thus more frequently end up in the PA group. Thus, more diabetics tend to increase the number of TT amputations and to increase the mortality.

Amputation level and mortality in PRVA and PA is thus determined by a number of factors in the population as well as the selection made by the surgeons according skill, organisation and attitude. We found that amputation stumps in patients previously undergoing revascularisation in an attempt to save the limb tended to have a higher risk of conversion to a higher amputation level. However, the conversion rate after PRVA (23%) (although significant), was only 10% higher than after PA (12.4%). It is important to emphasise that, when amputation is inevitable, outcome can be improved by rehydration and nutrition[31] and probably by objective determination of amputation level.[7] Finally, as amputations become fewer and more complicated, the organisation should be more centralised. This has been demonstrated in Dundee,[40] where a number of different amputation levels are used with excellent results.

In conclusion, this meta-analysis could not detect any difference in TT/TF ratio between PRVA and PA. However, patients after PRVA have a higher risk of conversion to a higher level compared to PA. The chance of having a successful transtibial amputation is approximately 58% for both groups. An aggressive approach to revascularisation seems justified.

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